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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,652	07/11/2001	Lisa Benincosa	P32185	7168

20462 7590 06/09/2003

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EXAMINER

CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/831,652

Applicant(s)

BENINCOSA ET AL.

Examiner

Theodore J. Criares

Art Unit

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:                                          |

## **CLAIMS 1-21 ARE PRESENTED FOR EXAMINATION**

Applicant's election without traverse of Group I, claims 1-15 in Paper No.7 is acknowledged.

Claims 16-21 are withdrawn from consideration.

### **DETAILED ACTION**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the administration of Avandia, does not reasonably provide enablement for the insulin sensitizers set forth in claim 15 since applicants admit that the dosage forms required for the treatment of diabetes II are larger than those required when administering Avandia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The dosages to administer such sensitizers as troglitazone or ciglitazone can not be determine from a reading of the specification. See claim 15 which are the compounds applicant deems can be administered in an amount, which is neither taught nor undisclosed in the specification.

#### ***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-25 are rejected under 35 U.S.C. 102(a) as being anticipated by applicants' admissions.

Applicants admit at page 3, lines 10-25 that insulin sensitizers are known in dosage forms which include 100 to 800 mg. of troglitazone, such as 200, 400, 600 or 800 mg dosages and from 5 to 50 mgs of pioglitazone.

The applicants' claims are drawn to administering an effective amount of an insulin sensitizer so as to provide a plasma concentration of the insulin sensitizer at threshold level within the range of effective plasma levels for the insulin sensitizer. A reading of the specification indicates that this is accomplished by administering a dosage of the sensitizer of from 2-12 mg in a pharmaceutically effective form (see page 3, lines 22-23) administered from 1-6 times per day. See page 8, lines 34 and 35. The sensitizer tested by the applicant was Avandia administered twice daily. The amount of dosage form known for pioglitazone, as admitted by the applicants at page 3, is 5 mg. This dosage form inherently would yield the same claimed effective plasma levels of Avandia as taught by applicants admission. For example administering pioglitazone twice a day in the dosage of 5 mg. per dose would inherently have the same effect as administering 4 mg of Avandia twice a day. Therefore, applicants' claims as drawn are anticipated by their admissions.

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None of the claims are allowed.

#### REMARKS

It is the policy of the Patent and Trademark Office (Office) to respect the proprietary nature of all trademarks and to make every effort to prevent their use in any manner which might adversely affect their validity. In this regard, the Manual of Patent Examining Procedure (MPEP) section 608.01(v) addresses the manner in which a trademark may appear in a Patent. Specifically, a trademark should be entirely capitalized.

It is believed the subject application contains the trademark Avandia which is not in compliance with the regulations. Accordingly an amendment is proper if in fact Amendia is a trademark.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

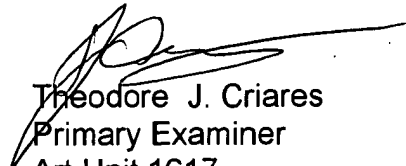
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

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Theodore J. Criares  
Primary Examiner  
Art Unit 1617,

tjc  
May 28, 2003